## REMARKS

### I. The Claimed Invention

The basic and novel characteristics of the claimed invention are defined by the expressly recited active agents which are formulated in a unit dosage form and administered to treat gastrointestinal orders.

Applicants maintain that the claimed invention was never intended to include NSAIDs as an active agent. In this regard, the Examiner's attention is respectfully directed to that section of the specification, at pages 14-20, entitled "Active ingredients", where the active ingredients of the claimed invention are disclosed. These active ingredients include (1) a $H^+,K^+$-ATPase inhibitor, (2) a gastric antisecretory prostaglandin and (3) a calcium channel blocker. ***There is no disclosure or suggestion that a NSAID is also an active ingredient of the claimed invention.*** Furthermore, in the following section of the specification, at page 20, entitled "Use of the preparations", it is disclosed that:

> The [claimed] dosage form may also be ***used*** in combination with other dosage forms comprising for instance...an NSAID...
> (Emphasis added)

In view of the entirety of the specification, e.g., the disclosures at pages 14-20, Applicants submit that it is abundantly clear that NSAIDs were never intended to be included as an active ingredient in the claimed dosage form. Rather, it was contemplated that the claimed dosage form could be ***used*** in the treatment or prevention of gastrointestinal side-effects associated with NSAID treatment. (See specification at page 1, lines 15-27).

Finally, none of the Examples of the claimed invention show a dosage form including a NSAID as an active ingredient.

**II. Claim Amendments**

Claim 1-4, 6-27, 31, 32, 35 and 38-40 are pending and have been rejected. Of these claims, only claim claims 1, 35 and 40 are independent.

As stated in Section I, above, the basic and novel characteristics of the claimed invention are defined by the expressly recited active agents which are formulated in a unit dosage form and administered to treat gastrointestinal orders.

Independent claims 1 and 40 have been amended to expressly state that the specifically recited active agents ***"are the only active agents in the claimed pharmaceutical dosage form"***. Thus, Applicants submit that the recitation of the open-ended transitional expression "comprising" does not change or affect the basic and novel characteristics of the invention defined in the balance of claims 1 and 40. For example, it is possible for the claimed dosage form to include unspecified excipients which are used to formulate the dosage form. However, the inclusion of such excipients would not affect the basic and novel characteristics of the claimed dosage form which is defined by the express recitation of active agents.

Therefore, the only active agents in the dosage of independent claim 1 are (1) a $H^+,K^+$-ATPase inhibitor, and (2) a gastric antisecretory prostaglandin. The only active agents in the dosage form of independent claim 40 are (1) a $H^+,K^+$-ATPase inhibitor, (2) a gastric antisecretory prostaglandin and (3) a calcium channel blocker. The other independent claim, i.e., claim 35, does not recite a transition expression. As expressly recited, the only active agents in the dosage form of independent claim 35 are (1) a $H^+,K^+$-ATPase inhibitor, (2) a gastric antisecretory prostaglandin, and (3) a calcium channel blocker.

**III. Claim Rejections – 35 U.S.C. §103**

Claims 1-4, 11-27, 35, 38 and 39 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of US 6,365,184 to Depui et al. ("Depui") in combination with US 6,387,410 to Woolfe et al. ("Woolfe").

Depui discloses and claims a unit dosage form including a proton pump inhibitor and a NSAID. Woolfe discloses a mixture of a NSAID and a prostaglandin to treat any side-effects associated with the administration of the NSAID. The Examiner alleges that it would have been obvious, at the time the claimed invention was made, to combine Depui with Woolfe to arrive at the claimed invention.

For the reasons given in Sections I and II, above, the claimed invention excludes unspecified active agents, e.g., NSAIDs. In contrast, the combination of Depui and Woolfe results in a dosage form characterized by a combination of a proton pump inhibitor and a NSAID. The combination of Depui and Woolfe does not suggest the claimed invention which excludes unspecified active agents such as NSAIDs. Therefore, the claimed dosage form is nonobvious in view of the cited combination of references.

For all of the foregoing reasons, withdrawal of the §103 rejection based on the combination of Depui and Woolfe is requested.

## IV. Claim Rejections – 35 U.S.C. §103

Claims 1-4, 11-27, 35, 38 and 39 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of Akira Tari et al. ("Digestive Diseases and Sciences, Vol. 42) ("Tari") in combination with Depui. Tari discloses a combination therapy including the administration of omeprazole and enoprostil. However, Tari does not disclose or suggest the possibility of formulating both actives in a unit dosage form (See specification at page 3, lines 13-25).

Accordingly, the Examiner relies on Depui for the disclosure of a unit dosage form comprising a proton pump inhibitor and a NSAID. For the reasons set forth in Section III, above, the combination of Tari and Depui does not suggest the claimed invention which excludes additional unspecified active agents such as NSAIDs which are required by Depui. Moreover, the secondary reference to Depui does not and cannot offer any suggestion or motivation to combine a gastric antisecretory prostaglandin analogue compound with a $H^+$, $K^+$-ATPase inhibitor. Specifically, the disclosure by Depui of a unit dosage form including a $H^+$, $K^+$-ATPase and a NSAID does not suggest the claimed dosage. At best, the Examiner's reliance on Depui is based on a standard of "obvious to try" which is not the proper standard for an obviousness rejection. The combination of cited references fails to provide the motivation to do what Applicants have done.

Withdrawal of the §103 rejection is requested.

## V. Claim Rejections – 35 U.S.C. §103

In the final Office Action, claims 1-4, 6-27, 31, 32, 35 and 38-40 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of the combination of Depui, Woolfe and US 5,582,837 to Shell ("Shell"). Shell is relied upon for its alleged disclosure of a dosage form containing a calcium channel blocker for the treatment of gastric diseases.

As noted by the Examiner, the expected result would be a single dosage form comprising a combination of a proton pump inhibitor, NSAID, calcium channel blocker and prostaglandin. However, the claimed invention excludes a NSAID. Therefore, the combination of Depui, Woolfe and Shell does not suggest the claimed invention.

Withdrawal of the §103 rejection is requested.

## CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance, which action is earnestly solicited.

Authorization is hereby given to charge any additional fee required in connection with the communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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